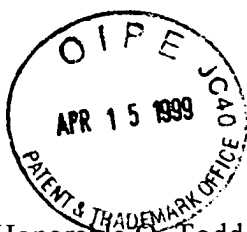




## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service



ASSISTANT SECRETARY

Food and Drug Administration  
Rockville MD 20857

99 MAY 27 AM 1:15

U.S. PATENT  
AND  
TRADEMARK OFFICERe: BeneFIX™  
Docket No. 97E-0168

APR 13 1999

The Honorable Q. Todd Dickinson  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 5,171,569 filed by British Technology Group Limited under 35 U.S.C. § 156. The patent claims the human biological product BeneFIX™ (coagulation factor IX (Recombinant)), product license application PLA 96-1048.

In the August 4, 1998, issue of the Federal Register (63 Fed. Reg. 41579), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before February 1, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

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cc: M.C. Meinert, Esq.  
Genetics Institute, Inc.  
Legal Affairs  
87 Cambridge Park Drive  
Cambridge, MA 02140

DEPARTMENT OF  
HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville MD 20857

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Washington, DC 20231

